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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,063	02/19/2004	Peter M. Allred	7678.816.2	2630

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EXAMINER

O CONNOR, CARY E

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/784,063	Applicant(s) ALLRED ET AL	
	Examiner Cary E. O'Connor	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/30/04, 6/22/04, 6/10/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 17-28, 30-34, 36, 38, 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382). Wiesel shows an article of manufacture comprising a shaped dental bleaching composition having a tray-like configuration comprising front side wall, a rear side wall, and a trough between the front and rear side wall (see Figs. 2 and 3). The composition further comprises an adhesive layer 12 comprising a substantially solid adhesive composition (paragraph 0030). The composition also comprises a bleaching gel 16, adjacent to an inner surface of the adhesive layer, comprising at least one dental bleaching agent (30 to 35% hydrogen peroxide), a tackifying agent (carbopol) and a gel carrier. The adhesive disclosed by Wiesel does not have increased adhesiveness to teeth when moistened. Chang shows an article of manufacture for bleaching teeth comprising an adhesive activation composition that provides substantial adhesive strength when hydrated by water. This adhesive activation composition comprising a tooth adhesion agent and at least one bleaching agent activator (paragraph 0061). This type of adhesive does not stick to the hands or face during application, thereby making the article easier to handle. It would have been obvious to one of ordinary skill in the art

at the time the invention was made to replace the adhesive of Wiesel with that taught by Chang, because the adhesive of Chang is easier to handle. As to claim 3, the composition has a horse-shoe configuration when applied to the dental arch. As to claims 4 and 36, since the article of Wiesel is in sheet form it inherently has a substantially straight longitudinal profile prior to use. As to claims 5 and 34, note that a portion of the trough of Wiesel has an approximate U-shaped cross section, as shown in Figs. 2 and 3. As to claim 7, Figures 2 and 3 show the bleaching composition 16 sized and configured so as to approximately terminate near a persons gingival margin. As to claims 8 and 41, note paragraph 0041 of Chang. As to claims 9 and 42, note that the bleaching agent activator of Chang can comprise a metal (paragraph 0061). As to claim 10, note paragraph 0071 of Chang which discloses that the tooth adhesion agent having a concentration of about 20% by weight of the adhesive composition. As to claim 11, note that the adhesive composition of Chang may include a humectant (glycerin, see paragraph 0067). As to claims 12-14, neither Wiesel nor Chang disclose the thickness of the adhesive layer. At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the adhesive layer with a thickness in the range of .01 to about 3 mm because applicant has not disclosed that this range of thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the thickness in the range claimed by applicant. As to claims 15, 17, 44 and 45, note that Wiesel discloses the addition of therapeutic medicaments or agents for treating sensitive teeth (paragraph

0045). As to claims 18-20, note the concentration of bleaching agent disclosed by Wiesel in paragraph 0034. As to claims 22-24, 32, 37 and 38, note the flexible barrier layer 20 of Wiesel that may be formed of polyolefin or polyurethane (paragraph 0037). As to claims 25 and 26, Wiesel discloses the thickness of the barrier layer as being 30 mil (paragraph 37). At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the barrier layer with a thickness in the range of 0.025 mm to about 1.5 mm because applicant has not disclosed that this range of thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the thickness in the range claimed by applicant. As to claim 27, note that Chang discloses a pouch for storage in paragraph 0062. As to claims 28 and 47, it is well known to provide a plurality of bleaching articles in a kit for use on multiple days. As to claims 31 and 48, note the method of use disclosed by Wiesel in paragraphs 0039 and 0040. As to claim 40, Wiesel discloses that the adhesive layer has a rigidity that partially contributes to structural support of the article (paragraph 0031). As to claim 43, note the concentration of bleaching agent activator disclosed in paragraph 0081 of Chang. As to claims 49-51, note that the adhesive of Wiesel is freeze-dried inherently removing at least a portion of the solvent.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382) as applied to claim 1 above, and further in view of Pellico et al (5,631,000). The bleaching gel of Wiesel is not anhydrous

prior to use. Pellico discloses an anhydrous bleaching gel. This gel improves packaging stability and reduces sensitivity during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the gel of Wiesel with the anhydrous gel of Pellico, in order to improve packaging stability and reduce sensitivity during use.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382) as applied to claim 1 above, and further in view of Andreiko (5,752,826). Neither Wiesel nor Chang disclose that a plurality of dental bleaching compositions are stacked and interested together. Andreiko shows a single use dental impression tray and discloses that a plurality of the trays may be stacked together for easy storage (column 8, lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to store the articles of Wiesel as modified by Chang in a stacked condition, in view of Andreiko, for ease of storage.

Claims 35, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382) as applied to claim 32 above, and further in view of Schwartz (6,089,869). The article of manufacture of Wiesel as modified by Chang is not initially horseshoe shaped prior to use. Schwartz shows a dental bleaching tray that is pre-formed in a horseshoe shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the article of Wiesel as modified by Chang in a horseshoe shape prior to use, in view of Schwartz, so that the article has a more customized fit thereby making it more

effective.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 17-34, 36-49, 51 and 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11-13, 17-41, 43-47, 51-55, 58 and 59 of copending Application No. 10/692,117 in view of Chang et al (2003/0194382). Claims 1 and 32 of the instant application does not include a tray like configuration as set forth in claims 1 and 39 in the copending application. It has been held that the elimination of an element and its function where not needed is obvious. *In re Karlson*, 136 USPQ 184 (CCPA 1963). Claims 1 and 32 of the instant application includes a bleaching agent activator that is not including in the claims of the copending application. Chang discloses a bleaching device having an adhesive layer including a bleaching agent activator (paragraphs 0060-0061). The activator shortens the time required for teeth whitening. It would have

been obvious to one of ordinary skill in the art at the time the invention was made to provide the article of manufacture set forth in claims 1 and 39 of the copending application with a bleaching agent activator in the adhesive layer, in view of Chang, in order to reduce the amount of time to whiten the teeth.

Claims 1, 4, 7-15, 17-28, 30, 36-38, 40-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 9, 10, 13-18, 20-36, 39-47, 53-56 of copending Application No. 10/728,525 in view of Chang et al (2003/0194382). Claims 1 and 32 of the instant application does not include a tray like configuration as set forth in claims 1 and 35 in the copending application. It has been held that the elimination of an element and its function where not needed is obvious. In re Karlson, 136 USPQ 184 (CCPA 1963). Claims 1 and 32 of the instant application includes a bleaching agent activator that is not including in the claims of the copending application. Chang discloses a bleaching device having an adhesive layer including a bleaching agent activator (paragraphs 0060-0061). The activator shortens the time required for teeth whitening. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the article of manufacture set forth in claims 1 and 39 of the copending application with a bleaching agent activator in the adhesive layer, in view of Chang, in order to reduce the amount of time to whiten the teeth.

Claim 16 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/728,525 in view of Chang, as applied to claim 1 above, and further in

view of Pellico et al (5,631,000). The bleaching agent of Chang is not anhydrous prior to use. Pellico discloses an anhydrous bleaching gel. This gel improves packaging stability and reduces sensitivity during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the agent of Chang with the anhydrous gel of Pellico, in order to improve packaging stability and reduce sensitivity during use.

Claim 16 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/692,117 in view of Chang, as applied to claim 1 above, and further in view of Pellico et al (5,631,000). The bleaching agent of Chang is not anhydrous prior to use. Pellico discloses an anhydrous bleaching gel. This gel improves packaging stability and reduces sensitivity during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the agent of Chang with the anhydrous gel of Pellico, in order to improve packaging stability and reduce sensitivity during use.

Claim 29 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/728,525 in view of Chang, as applied to claim 1 above, and further in view of Andreiko (5,752,826). Chang does not disclose that a plurality of dental bleaching compositions are stacked and interested together. Andreiko shows a single use dental impression tray and discloses that a plurality of the trays may be stacked together for easy storage (column 8, lines 5-6). It would have been obvious to one of

ordinary skill in the art at the time the invention was made to store the articles of claim 1 as modified by Chang in a stacked condition, in view of Andreiko, for ease of storage.

Claim 35 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 39 of copending Application No. 10/692,117 in view of Chang, as applied to claim 39 above, and further in view of Schwartz (6,089,869). The article of manufacture of Chang is not initially horseshoe shaped prior to use. Schwartz shows a dental bleaching tray that is pre-formed in a horseshoe shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the article of claim 39 as modified by Chang in a horseshoe shape prior to use, in view of Schwartz, so that the article has a more customized fit thereby making it more effective.

Claim 35 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/728,525 in view of Chang, as applied to claim 35 above, and further in view of Schwartz (6,089,869). The article of manufacture of Chang is not initially horseshoe shaped prior to use. Schwartz shows a dental bleaching tray that is pre-formed in a horseshoe shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the article of claim 35 as modified by Chang in a horseshoe shape prior to use, in view of Schwartz, so that the article has a more customized fit thereby making it more effective.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 571-272-4715. The examiner can normally be reached on M-Th 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Cary E. O'Connor
Primary Examiner
Art Unit 3732

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